CARDIOLINE®

ar1200view

User's Manual

CE 0470

English

This User Manual has been prepared with the objective of giving the user all the necessary information to make the best use of the **CARDIOLINE® ar1200view**.

General information

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CARDIOLINE® product support services

For any questions about a *CARDIOLINE* product:

- ✓ consult the documentation and other printed material included in the package;
- ✓ consult any guidelines available.

If you find no solution, you can obtain further information by contacting your *CARDIOLINE* supplier.

Before calling, check you have the available documentation to hand and the product nearby. It may also be necessary to supply the following information:

- ✓ serial number and product reference number, if available;
- ✓ type of hardware available, including any network hardware fitted;
- ✓ operating system used, for software products;
- ✓ exact contents of any error messages displayed;
- ✓ description of the operation being executed when the problem occurred;
- ✓ description of any action taken to solve the problem.

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1 Introduction

ar1200view is an electrocardiograph with dual power supply (mains and rechargeable internal batteries), whose basic configuration allows for the following functions:

- ✓ ECG recording in automatic, manual, and timed mode;
- ✓ real-time display of the ECG signal on the built-in graphic display in 3, 6 channel format;
- ✓ reproduction of the ECG signal on several different formats of 120mm paper by means of the high resolution thermal printer: 3, 3+R, and 6 channels;
- ✓ sorting of the tests according to clock, dater and alphanumeric keyboard to manage user and patient data;
- ✓ storage of the most recent automatic recording and print of additional copies;
- ✓ setting of up to 4 different user profiles to tailor device functions to differing requirements.

ar1200viewv can be updated with:

- "memory option": storage of up to 40 full ECG exams, with no need to print out immediately on paper ("paper saving" mode);
- "ECG parameters option": automatic ECG parameter measurement program;
- "ECG signal interpretive option": a useful and dependable diagnostic support;
- "arrhythmia option": a program enabling detection of arrhythmia events during continuous recording;
- "HRV analysis option": a program enabling detection of variations in heart rate;
- "PC archive option": for saving the exam to archive stored in a personal computer running CARDIOLINE software. The data upload to the PC is made by use of the wireless "IR" interface; no direct connection to the PC is required.
- "PC-ECG option": for real time display of the twelve leads on your computer screen to allow management of patient medical records and archiving of exams in digital format using CARDIOLINE software. The software has an optional module for automatic interpretation of the ECG signal.
- "Emergency option": allows to perform and eventually transmit, an ECG exam taken in emergency situation in completely automatic mode.

For more information on available options, contact your selected dealer.

THANK YOU FOR BUYING CARDIOLINE!. Your new computerised electrocardiograph CARDIOLINE® has been designed and built in compliance with the applicable regulations in force at the time when et medical devices SpA, Cavareno (Trento) - ITALY drew up this manual. et medical devices operates in accordance with the requirements for quality management systems defined by EN ISO 9001: 2000 and EN ISO 13485: 2003 standards. The system is covered by a Nemko Certification AS (Cert. N. 800278). Your new electrocardiograph has also been built in compliance with the Medical Device Directive 93/42/EEC and is therefore marked by the relevant CE0470 mark.

1.1 How to read the manual

In order to ensure the **CARDIOLINE® ar1200view** is operated in a safe and correct manner, and to appreciate its ease of use and high reliability, **the user instructions must be read carefully**.

This documentation describes the functions of your electrocardiograph including those provided by all the possible "options" available. It is therefore possible that some of the functions described may not be present in the model you have purchased. For details of the options, consult the "firmware configuration" chart that accompanies each individual appliance.

This symbol allows you to identify the functions **not** provided on all models, which must be requested specifically at the time of purchase.

This symbol allows you to identify the functional, behavioural and operational aspects that may be conditioned by the type of configuration selected during the step of *"Preparation for use: the menu"*.

When a given key is depicted in the body of a sentence or a paragraph, *press* the corresponding key on the device to perform the action.

The structure of this manual allows you to approach the use of the electrocardiograph according to your level of knowledge. If you have already had experience with **CARDIOLINE®** equipment, the initial fast-track part of each paragraph will allow you to begin working immediately. In the continuation of the paragraph, on the other hand, the single aspects of operation are discussed in more depth.

The manual gives detailed information on the use of the model **ar1200view** in traditional ECG procedures, and an introduction to the use of particular functionalities involving interaction with software and a Personal Computer. For instructions on the use of the software applications for Personal Computer, consult the special online guides.

The quick guide to the electrocardiograph (at power-up the display shows

the message " ? Press 1 ": to obtain the printout) sums up the operations linked to the single commands presented in the manual.

Further information and clarifications can be requested directly from:

CARDIOLINE® - Supporto Prodotto

Strada Rivoltana Nuova, 53, I - 20060 Vignate (MI) ITALIA

e-mail: et.service@etmed.biz

tel. +39 02 95 05 181 fax: +39 02 95 66 013

1.2 Information and recommendations relating to safe use

- The electrical system used by the device must be in accordance with the standard in force.
- Always use the equipment according to the instructions in this manual.
- The device is equipped with a set of standard accessories. For reasons of safety, reliability and conformity with the Medical Devices Directive 93/42/EEC, use only original accessories or accessories approved by the manufacturer.
- The device is equipped with a special long-life thermal head writing system, which allows maximum writing precision. To avoid frequent and costly replacements and repairs, always use the original paper or paper approved by the manufacturer. The manufacturer will not accept liability for any damage to the device or any other adverse effect caused by the use of unsuitable paper.
- Do not subject the device to impact or excessive vibrations.
- Do not allow liquids to penetrate inside the device. If this should accidentally occur, have the device tested by an Authorised Assistance Centre to verify its functional efficiency, before using it again.
- Make sure that the value of the supply voltage corresponds to that indicated on the data plate of the device.
- If you are using the device in connection with others, ensure that: all connections are made by skilled persons; all connections comply with safety regulations; all other devices connected respond likewise to regulations. Non-compliance with regulations can cause physical harm to the patient connected and to the person operating the device. Should it be difficult to obtain the necessary information for assessing the risk of the individual connections, apply directly to the manufacturers concerned or avoid making the connections.
- In the event of other equipment being connected directly or indirectly to the patient, check for the possible risks caused by the sum of the leakage currents on the body of the patient.
- The device is protected against defibrillation discharges in accordance with IEC standard 601-1-25; to ensure that the signal is restored, use

only original electrodes or electrodes responding to IEC and AAMI standards.

- If an electrosurgical scalpel is in use, the patient cable should be disconnected from the device.
- At all events, when defibrillators or high-frequency surgical devices are being used at the same time, it is essential to take the greatest care. If there is any doubt when such devices are in use, disconnect the patient from the electrocardiograph temporarily.
- The device recognises the impulses generated by a pacemaker and does not interfere with its operation, as prescribed by standards in use at the time of drafting this manual.
- Avoid exposing the equipment to extreme temperatures, excessive dust or dirt, and very salty or damp environments; observe the ambient conditions described in detail under the "Technical specifications" heading.
- Periodically check the efficiency of all accessories and of the device itself. Contact the Authorised Assistance Centre whenever the device seems to be operating irregularly. To prolong the life of your device, have it checked periodically by an Authorised Assistance Centre.
- **Warning**: The electrocardiograph can be used for intracardial applications.
- **Warning**: It is therefore necessary, before activating the equipment, to make sure of the connection to ground (normally secured by the power supply cable). If grounding of the main electrical service is not certain, do not connect the device and use it powered only by the rechargeable internal battery.
- **Warning**: do not use the device in the presence of anaesthetics or volatile gases!
- **Warning**: devices for medical applications must be used only by persons who by virtue of training or practical experience are able to ensure maximum safety and effectiveness in operation. Operators must in any event read this manual carefully and familiarise themselves with the instrument before using it on a patient.
- **Warning**: the indications obtained using automatic interpreting programs or other diagnostic aids must be reviewed and countersigned by a qualified medical person!
- **Warning**: the device is provided with an IR interface for the transfer of data to other devices. The IR interface must not be masked, even accidentally, as this will adversely affect its capability and its operation, interrupting and preventing the correct flow of data.
- The manufacturer will acknowledge liability for the safety, reliability and functional efficiency of the device only if:

  modifications and repairs are performed by the manufacturer or by an Authorised Assistance Centre;

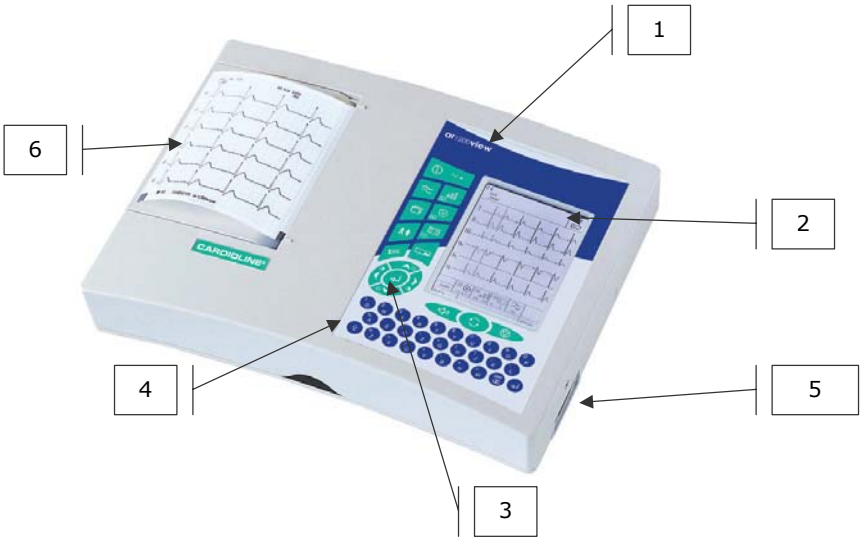
  the AC mains power supply of the building responds to current regulations;

  the device is operated according to user instructions;

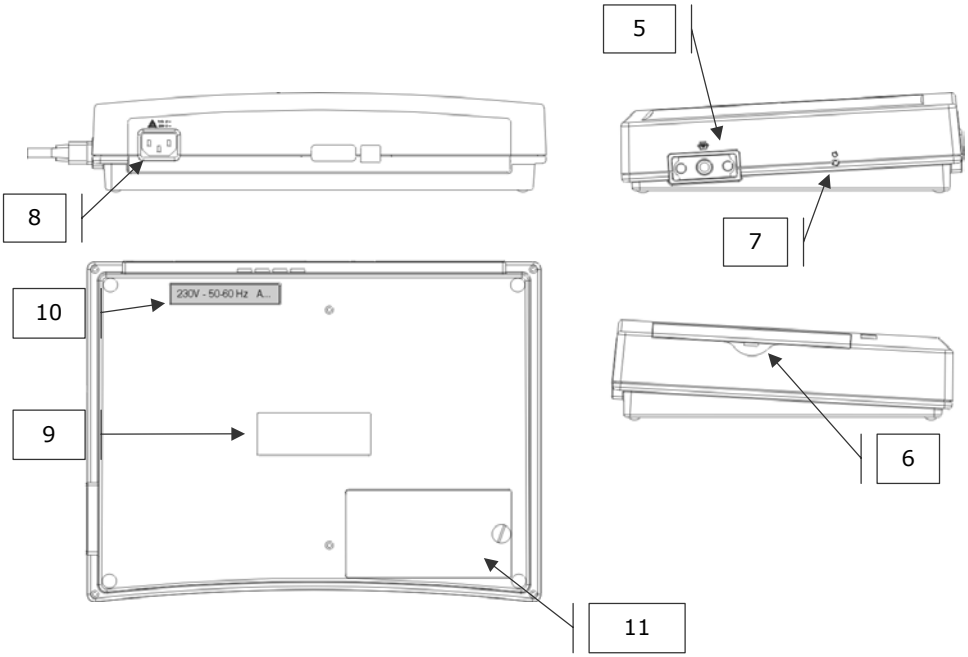
  any accessories in use are those approved by the manufacturer.

1.3 The electrocardiograph

Front view



Side view and bottom



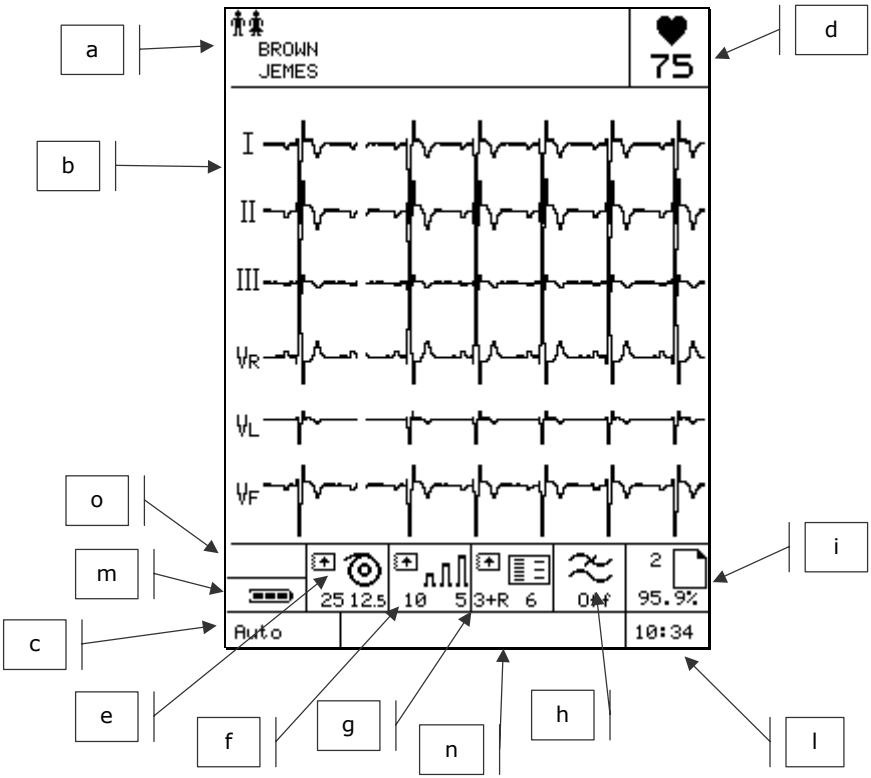
Parts, symbols and controls

2. Keyboard:

Function key	Messages & Symbols displayed / Associated LED
on/ off	- LED on: device connected to mains power; internal battery charging
	- "full" symbol: battery charged - "part empty" symbol battery power less than 30% - "empty" symbol: internal battery flat; the device must be connected to the mains power for recharging
select start operating mode	- Indicated electrodes not connected or insufficient contact; saturation
interrupt current operation; stop	
Select operating mode	Auto - Automatic recording
	Man - Manual recording
	Personalized - Recording mode selected in configuration phase ("Personalize mode")
Select ECG display format	❒ Automatic mode: available formats - 3, 6 ❒ Manual mode: available formats - 3, 6 - In manual mode, print and display format selections are consistent with each other
Select print format	❒ Automatic mode: available formats - 3, 3+R, 6 ❒ Manual mode: available formats 3, 6, - In manual mode, print and display format selections are consistent with each other

AC mains and muscle interference filter	❒ On display: On / Off ❒ On paper: - Filter on
Select ECG scroll speed on display	Available speeds: 12.5 – 25 – 50 mm/s
Select paper scroll speed	Available speeds: 5, 25, 50 mm/s
Select ECG recording sensitivity on screen	Available wavelengths: 5, 10, 20,
Select ECG recording sensitivity on paper	Available wavelengths 5, 10, 20, Automatic
Enter patient data	- Displays patient data file
Copy last recording	
Store in PC	-

2. Display: to display the ECG signal, control operations, patient data, report data and settings.



In normal operating mode:

a. Patient data area: displays Last Name (first line) and First Name (second line).

b. ECG signal display area Each lead is preceded by its name

c. Selected operating mode. *In Menu mode,* ▲▼◄► *indicates scroll functions enabled.*

d. Heart rate.

e. Selected speed of printing (value on left) and display (value on right)

f. Selected sensitivity of printing (value on left) and display (value on right)

g. Selected print format (value on left) and display format (value on right)

h. Filter in place/not in place indicator.

i. Number of tests stored and space available , in Autotimer, HRV and Arrhythmia mode , it displays test timing.

l. Time display.

m. Battery status indicator

n. Operating information and error message area. *In Menu mode, it indicates enabled keys and any additional options.*

o. In Autotimer, HRV, PC-ECG, Store in PC modes, Arrhythmia displays a progress bar.

3. Display control keyboard.

➢ Cancel operation, back to previous menu.

➢ scroll menu and information. In main screen, scroll leads on display

➢ Access to Menu. It scrolls multiple selections, if any, symbol displayed.

4. Alphanumeric keyboard for patient data management.

➢ Characters that can be displayed in sequence are associated to each key.

➢ Deletes texts before cursor.

➢ Confirms operation.

5. Patient cable connector.
6. Paper compartment door.
7. Reset button : used to re-establish normal operating conditions in the event of an error that cannot be managed using the keyboard.
8. "Mains line" connector.
9. Identification plate. Please, refer to the information shown on this plate during any communication with the Authorised Support Centres.
10. Rated voltage plate.
11. Rechargeable battery compartment door.

2 Installation and initial preparation

This section describes the operations to be performed before using your new **CARDIOLINE® ar1200view** electrocardiograph. Suggestions are given for "*selecting the installation site*" and "*recommendations for safe use in conformity with current statutory regulations*" are indicated. Also introduced are the operations involved in preparing the electrocardiograph for use, such as "*loading the thermal paper*", "*power supply"; "control and management of the rechargeable internal battery*", "*switching on and off*", "*the menu*", "*set-up*".

2.1 Selecting the installation site

Your electrocardiograph complies with European directives on electromagnetic compatibility. The absence of emissions damaging to radio and telecommunications transmissions is therefore assured, as also is protection from interference emitted by other systems and equipment Nevertheless, in order to protect your device from other equipments not in conformity with the aforementioned directives:

- avoid the use of mobile phones near the electrocardiograph;
- place the electrocardiograph as far as possible from electrical power lines and sources of static electricity. The ECG signal can be disturbed if the electrocardiograph is placed near sources of high voltage or electricity lines;
- avoid placing the electrocardiograph close to other diagnostic or therapeutic equipment (e.g. X-ray machines, ultrasound machines, electrically operated beds, etc.) that could be a source of excessive interference and ECG signal distortion;
- if it is impossible to position the electrocardiograph at a distance from other electrical equipment, switch the other equipment off while recording an ECG.

Also, to avoid the effect of ambient conditions when recording ECG:

- record in a room where the temperature is between 20 and 25 degrees Centigrade. This precaution prevents the patient from feeling cold, which could increase shivering and contribute to muscle tremor;
- record using the battery, disconnecting the device from the mains power supply. This avoids presence of mains power disturbance of the recorded ECG signal.

2.2 Loading the thermal paper

CARDIOLINE® ar1200view is able to reproduce the ECG signal both on thermal paper in rolls and on thermal paper in packs. No particular configuration procedure is required. To correctly load the two types of paper:

If using paper in rolls:

a. Open the paper compartment using a coin or a similar object, remove the "roll guide" hub and the "pack guide". To avoid losing the "guide", place it in a safe place. *If replacing an empty roll, retrieve the core before throwing away the empty roll.*

b. Insert the hub in a new paper roll (1) and house it in the paper compartment by positioning the pins in their specific guides (2). *Make sure that the black mark on the paper is in the upper part of the roll.*

c. Position the paper by centring it between the two paper-guides (3). Close the cover with the paper positioned between the rubber roller and the device case (4).

If using paper in packs:

a. Open the paper compartment using a coin or a similar object, remove the "pack guide" and the "roll guide" hub. To avoid losing the "guide", place it in a safe place.

b. Prepare a new pack (1) and house it in the paper compartment. *Make sure that the red mark on the paper is on the upper left part of the pack.*

c. Position the paper guide plate (2) onto the pack.

d. Position the paper exactly in the centre between the two paper-guides (3). Close the cover with the paper positioned between the rubber roller and the device case (4).

Warning: *For reasons of safety the device must be used only with the paper compartment cover duly closed.*

Warning: *use only original thermal paper or paper approved by the manufacturer. The use of paper that does not respond to the manufacturer's specifications could jeopardise the correct operation of the device.*

2.3 Power supply; control and management of the rechargeable battery

Your electrocardiograph uses a dual power supply system: AC supply mains and rechargeable NiMh battery.

The rechargeable battery, which consists in a pack with 5+5 elements, is housed in the special-purpose compartment located at the sliding bottom of the device, and is protected against short circuits.

Warning: *before using the device, it is necessary to go through a complete cycle of recharging of the battery!*

Before connecting the electrocardiograph to the AC supply with the cable supplied, make sure that the device supply voltage and the mains voltage are the same.

Warning: *the internal feeder of the device is classified under Class I.*

Warning: *when the device is connected to the mains, the battery is automatically recharged during use.*

To gain maximum benefit from the characteristics of the dual power supply system, follow the indications given below.

Recharging the battery

The battery must be recharged when the power indicator symbol is partly empty : the reserve charge is lower than 30%.

Connect the electrocardiograph to the mains: LED lit. Complete battery recharging requires at least 18 hours.

For longer life, the batteries should be allowed to run down and then be recharged completely at least every two months.

A complete recharge allows the recording of up to 300 complete ECGs (automatic recording mode, 3-channel print format, 25 mm/s speed).

Note: recording with different print format the maximum number of tests recorded can change.

When the batteries are run-down (symbol), it is still possible to make an ECG recording by connecting the device to the *AC* supply.

Warning: *do not dispose of run-down batteries in the environment. Use only original batteries supplied by the manufacturer. The average life of the batteries is about one year.*

Warning: *the device must be connected only to mains equipped with earth connection executed in compliance with applicable regulations.*

2.4 How to switch on the electrocardiograph

- for at least two seconds.
- The display turns on showing the "Operation Profile" screen. When the booting procedure is completed, the ECG signal and the settings selected are displayed on screen. Now you can use the device.

Warning: *if the symbols and are displayed, internal power is insufficient and the battery must therefore be recharged by connecting the device to the mains (see heading "Power supply; ..."). The battery will recharge even if the device is in use.*

2.5 How to switch off the electrocardiograph

The display turns off. The settings for the last recording remain stored in the memory. To see the effect of switching off on the last automatic recording see "Copy an automatic ECG recording".

Warning: *switching off is not enabled as specified in § "Auto power off". In these cases, first stop the device* *and then switch off.*

Auto power off

The procedure is enabled only after the current operation has been completed.

- After 10 min. have elapsed without any key being pressed: reserve power > 30%.
- After 1 min. has elapsed without any key being pressed: reserve power between 15 and 30% .
- After 10 secs have elapsed without any key being pressed: reserve power < 15% .

If the auto power off function is enabled the relative settings will be stored.

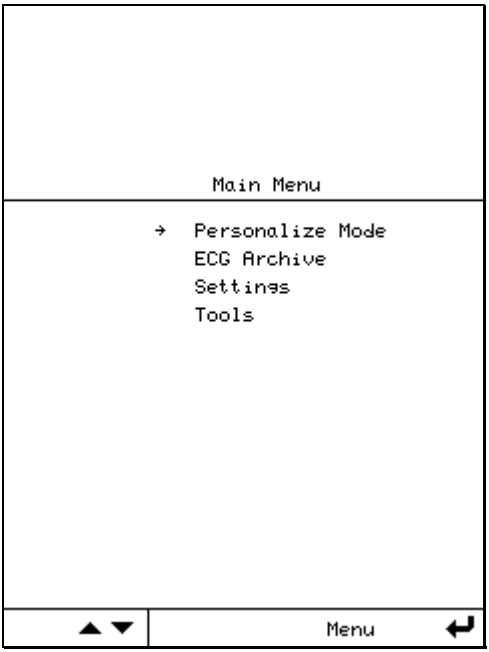
Auto power off is inhibited if:

- a recording is in progress in "ECG autotimer" mode;
- a recording is in progress in PC-ECG mode;
- a recording is in progress in HRV mode;
- a recording is in progress in Arrhythmia mode;
- during the self-test routine;
- during "set-up".

3 Preparation for use: the menu

3.1 How to access the menu

to access the menu from the main screen.



to scroll through the menu items.

executes the action associated with the symbol ↵ displayed: access the lower level menu, select and confirm.

to scroll multiple selections. If available, symbol ⊟ displayed.

to return to the previous level.

3.2 Structure of the menu

The menu is organised in four sections: “Personalize mode”; “ECG archive”;

"Settings" and "Tools". The following tree layout of the menu illustrates the different levels of exploration possible, and the features that can be selected. Details on the single items are given in subsequent headings.

- *Personalize mode*
  - *Emergency*
  - Paper Saving ☑
  - PC ECG ☑
  - Arrhythmia Monitor ☑
  - HRV analysis ☑
  - ECG autotimer ☑
- *ECG archive*
  - View
    - PC archive
    - Print
    - Delete
  - PC archive
  - Print list
  - Clear
- *Settings*
  - Operation Profile
    - Select Profile
      - Profile 1
      - Profile 2
      - Profile 3
      - Profile 4
    - Set Profile (Change / New)
      - User Data
        - Profile Name
        - User - Institution
        - Ward/Dept. Name
      - 3+R Print Report
        - Auto 3+R
          - Simultaneous
          - Sequential
        - FP Rhythm Leads
      - Lead Sequence
        - Standard
        - Cabrera
        - Personalized
      - Number of auto pages
        - 1 page
        - 2 pages
      - Configure Analysis ☑
        - ECG measurements
          - Summary

        - ST amplitudes
        - Templates
    - ECG interpretation
        - Summary
        - Rhythm
        - Interpretation
        - Measurements
        - Templates
    - None
- Configure Copy
    - Complete
    - ECG Only
    - Analysis Only ☑
- Archive Management ☑
    - Save
        - Automatic
        - Request
        - None
    - Deleting
        - Manual
        - Automatic
    - Autotrx last ECG
        - Yes
        - No
        - Emergency only
    - Analisi HRV ☑
- HRV analysis ☑
    - Duration: x
    - Lead
- Autotimer
    - No. Intervals: xxx
    - Duration of intervals: xxx
    - Type of print
        - From memory
        - Real time
    - Print format
        - Auto
        - 3 leads
            - Lead Selection
        - 6 leads
            - Lead Selection
- Arrhythmia
    - RR Advance
    - RR Delay
    - Print Advance
    - Print Delay
    - Event Print
    - ARR Lead

- Print delay
  - Yes
  - No

- General
  - Date \ Time
  - Measurement Units
    - Cm / Kg
    - Inch / Pound
  - Mains filter
    - 50 Hz
    - 60 Hz
  - Display
    - Brightness
    - Contrast
  - Recorder ID
- Password (only numerical)

- *Tools*
  - About
  - Configuration Print
  - Default Configuration
  - Self-test
    - User
      - Display
      - Keyboard
      - Printer
      - Memory
      - About
    - Service
      - Only available to Technical Service

3.3 Menu-activated operation and personalization of the electrocardiograph

Listed below are the operating and configuration details associated with the single items in the menu. To operate the menu refer to the heading "*How to access the menu*".

"Personalize mode" ☑

The menu allows one of the enabled modes to be added to the direct selection of traditional operating modes (Automatic and Manual) The mode selected is displayed in the lower left corner of the main screen.

Options / Actions available	Description
☑ Emergency	The recording starts immediately pressing "start" key. If the automatic interpretation is enabled analysis will be performed considering a person of 35 years old gender male.

☑ Paper saving	The ECG trace is recorded and saved without any hard copy of the signal generated. The steps and the quality of the recording are monitored through messages in the display. Thereafter, the recording can be printed or saved to PC archive. Feature associated with “memory” option.
☑ PC-ECG	The twelve ECG leads are displayed in real time on your Computer screen where, thanks to the CARDIOLINE software (Real Time ECG), it is possible to perform all the ECG recording operations.
☑ Arrhythmia Monitor	The ECG signal is acquired in continuous mode and then printed in compressed format. Any arrhythmic phenomena are highlighted on the trace.
☑ HRV analysis	The signal is acquired and then reprocessed, indicating the parameters and trends of the variation in heart rate.
ECG autotimer	ECGs are recorded automatically at user-defined intervals in “Settings” menu .

The “ECG archive” ☑

The menu allows the main archive management functions to be operated.

Options / Actions available	Description
View	Displays the ECG list contained in the archive. Scroll the list and select an exam/patient. The user can now: 1. Archive the selected exam to a Personal Computer (“ArchPC”); 2. Print the selected example (“Print”); Delete the exam selected (“Delete”).
PC archive	Transfers and saves all stored exams to PC.
Print list	Prints the list of exams currently in the memory.
Empty	Deletes all exams held in the memory. A confirmation message is displayed.
Search	Searches a patient (search key: Name) in the archive.

“Settings”

The "Settings" menu allows different users to configure the functions of the electrocardiograph as best suits their individual working methods. Configurable characteristics are grouped together in three menus: “Operation profiles”, “General” and “Passwords”.

"Operation profiles"
Up to four different Operation Profiles can be saved. This facility enabled the recorder to be modified for different use requirements in just a few seconds.
Accessing the "Operation Profiles" menu the user can:
- recall an existing profile: "Select Profile".
- The list of saved Profiles is displayed. Select the desired Profile; the recorder settings are changed accordingly.
- set a new profile: "Set Profile".
- A new Profile ("New") can be created, changed ("Change") or deleted ("Delete"). to select the desired option, to confirm.

The parameters that can be associated to each profile are listed below.

Options / Actions available	Description
User Data	A Profile Name (8 characters), User/Institution Name (30 characters), Ward/Dept. Name (16 characters) can be entered. User Name and Ward/Dept. ID will be printed on all printed documents and sent to the PC when saved. The profile name is used to retrieve the settings.
Patient data management	However, patient data can be entered and updated at any time . The following data items are present in the file: o Patient ID o Last Name o First Name o Date of Birth o Sex o Last Name 2 o Blood Pressure o Height o Weight o Type o Medications o Notes o Ward/Department
3+R Print Report Management	- "Auto 3+R" The signal representation mode can be selected when a "3+R" format is selected. Two options are available: 1. "simultaneous": all 12 leads of the 3x4 part have the same time reference; 2. "sequential": the 12 leads of the 3x4 part are represented in time sequence. - "FP Rhythm Leads" The reference lead can be set.

Lead Sequence	Leads sequence. The sequence of leads printed can be selected. As well as modifying the order in which the leads are printed out, the selection also influences the rhythm lead selection menu. Three options are available: 1. Standard; 2. Cabrera. 3. Personalize: a special sequence can be set.
☑ Analysis configuration	The type of processing of the ECG trace acquired in automatic mode can be selected. The choice influences the type of document printed. Two configuration menus are available, linked to the type of automatic processing available: "ECG Parameters" and "ECG Interpretation". Processing may also be disabled by selecting "None". Inside the single menus to enable/disable a section. - "ECG Parameters". "Summary" represents the minimum report and cannot be de-selected. The following are reported: date and time of recording, patient data, note field, main ECG parameters calculated (heart rate; rhythm type; P, QT, QTc, PR, QRS and QTr wave amplitudes; frontal vectors; axes). “ST Measurements” printout of table of ST depression values on the twelve leads. “Templates”: printout of templates relative to the twelve leads. "ECG Interpretation". “Summary” represents the minimum report and cannot be de-selected. The following are reported: date and time of recording, patient data, if inserted, note field, ECG parameters calculated, frontal vector, indication of normality. “Rhythm Analysis”: print rhythm strip and diagnosis. “Interpretation” processing and printing out of ECG interpretation. In particular: atrial diagnosis, repolarisation disorders, atrial blocks, QRS-T evaluation. “Parameters” print complete ECG parameters table. “Templates”: printout of templates relative to the twelve leads.
Configure Copy	The "Copy" key can be configured. 1. “Complete”: the last automatic recording is printed out in full. 2. "ECG only": only ECG of last automatic recording is printed out. 3. “Analysis only”: only analysis of last automatic recording is printed out (if available).
☑ Archive management	ECG traces can be stored in different ways and memory status can be checked. When operating in “Paper Saving” mode, the saving function is always automatic. “Save” “Automatic”: traces are saved automatically when the scan is completed, with no action by the operator. The operation is indicated on the display by messages such as: “Saving...” and “ECG saved”. “Upon request”: at the end of recording, the patient’s file is shown, where the option “Save&Exit” is available. Press ↵ to proceed. If the test does not have to be saved, select “”Confirm&Exit”. A copy of the test will still remain available until a new recording is made or the device is switched off. “None” saving disabled.

	"Delete" "Manual" files can be deleted using the delete function on the Look in ECG archive menu. "Automatic" archive files are deleted automatically after successful transmission to a PC with the ArchPC function. "Auto-transmission last ECG" "Yes": last stored ECG will be automatically sent "No": no auto-transmission "Emergency only": only last stored ECG acquired in Emergency mode will be automatically sent .
☑ HRV analysis	The following can be set: duration of the test (1 to 5 minutes) and reference lead for analysis.
ECG Autotimer	The following can be set: number of recordings (intervals); duration of intervals (i.e. time between recordings); print delay (timed prints and manually activated prints between two intervals are referred to a sample acquired 10 seconds earlier); number of leads being printed: twelve (in format set), three or six (selectable).
Arrhythmia	The user can set: - the RR advance (in percentage); - the RR delay (in percentage); - the Print Advance: how many seconds of signal to be printed as reference normal ECG before the first event (min 2 sec. max 10 sec.); - the Print Delay: how many seconds of normal ECG after the last event (min 2 sec. max 10 sec.); - Arrhythmia monitor: enable the printout of the abnormal ECG during the test.; - Event Print: enable the abnormal ECG printout during the test; - ARR Leads: select lead full disclosure report.
Print Delay	It could be possible enable/disable 10 s. print delay, referred to a real time event.

"General"

Options / Actions available	Description
Date \ Time	Accessing the date/time programming masks. Use number keys for settings.
Units	Set units to be used for management of numerical patient data (Weight and Height). Two options are available: cm, Kg; inch, pound.
Mains filter	To ensure the device operates correctly select the mains frequency in the area of use. Two options are available: 50 Hz, 60 Hz.
Display	"Brightness" and "Contrast" may be set according to the environmental conditions of use. It is possible to modify bright and contrast pressing simultaneously Shift+ arrows, from main menu.
Recorder ID	A numerical ID (5 characters) for the recorder being used can be entered.

"Password"

A password (maximum 8 characters) can be entered, that will be requested to access the archive (if any), to set/change Use Profiles or to restore the factory configuration (default). If you do not wish to use the protection system, leave the "Password" field blank.

Warning: *to change or disable a Password, you need to know the current active Password. It is therefore suggested that you carefully store the protection key used. If you lose it, contact the nearest Service Centre.*

"Tools"

The "Tools" menu allows the user to access system related information and enable the self-test and setting functions of the device.

Options / Actions available	Description
About	Displays the recorder identification data, software version installed and language.
Print Configuration	To print the general recorder configuration and use profiles entered.
Default Configuration	To restore the ECG to factory configuration, cancelling the settings selected.
Self-test	There are two self-test menus available: "User" and "Service". See "Maintenance" chapter for details.

4 Preparing for an ECG recording

This section describes the preliminary operations required when recording an at-rest electrocardiogram with the **CARDIOLINE® ar1200view** electrocardiograph. In particular, indications are given for "*connecting the patient cable*", "*preparing the patient*", "*applying the electrodes*". Also illustrated are the necessary procedures for choosing the correct recording parameters, such as "*speed, sensitivity and introduction of the filter*".

4.1 Connecting the patient cable

Connect the terminal plug of the patient cable to the connector identified with the symbol , positioned on the right side of the device.

Note: *to avoid breaking the patient cable, remove it from the connector gripping it by the plug, and without tugging.*

Warning: *the device is protected internally against defibrillation discharges; restoration of the signal is guaranteed as long as original electrodes are used. To ensure conditions of safety are always maintained, use only original accessories.*

4.2 Preparing the patient and applying the electrodes

Careful preparation of the patient and correct positioning of the electrodes are fundamental in obtaining an ECG recording of high quality.

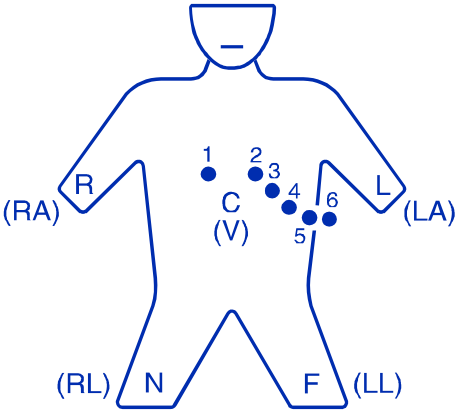
- ✓ First, make sure the patient is comfortable and relaxed and does not feel cold. The individual should lie back on a suitably large couch with arms and hands extended along the sides of the body: this will minimise the likelihood of the ECG trace being affected by muscle tremor.
- ✓ Clean the skin thoroughly with alcohol or ether at the areas where the electrodes will be placed.
- ✓ Connect each colour-coded plug of the patient cable to the respective electrode, observing the colour-position matches indicated below:

Colour	***Symbol***	***Electrode position***
Red	R	Right arm
Yellow	L	left arm
Green	F	Left leg
Black	N	Right leg
White - Red	C1	V1
White - Yellow	C2	V2
White - Green	C3	V3
White - Brown	C4	V4
White - Black	C5	V5
White - Violet	C6	V6

- ✓ Apply a small amount of electrocardiograph conductive gel to the area of the skin that will be in contact with the electrode, spreading it

carefully and evenly (this is not necessary when using disposable electrodes with built-in gel).

✓ The following figure shows the standard positioning of the electrodes.



Standard positioning of the electrodes

V1: on the 4th intercostal space, right parasternal;

V2: on the 4th intercostal space, left parasternal;

V3: on the 5th rib, between V2 and V4;

V4: on the 5th intercostal space, left hemiclavicular;

V5: on the left anterior axillary, same level as V4;

V6: on the left mid-axillary at the level of V4;

Peripheral electrodes: generally a few centimetres above ankles and wrists.

Warning: *make certain that the conductive parts of the electrodes are not in contact one with another or with other metallic parts. In any event, silver and silver chloride electrodes are designed and manufactured in such away as to minimise the likelihood of accidental contact between conductive parts and external metal objects. Ensure that the device is not affected by disturbances originating from the AC mains power supply (see "Initial preparation").*

4.3 Select recording characteristics operating mode, display and print format, speed, sensitivity, filter

Operating mode

The available recording modes (Operating mode) depend on the active configuration of the electrocardiograph.

to select the desired mode; the corresponding choice is displayed on the screen. The options available are: Automatic, Manual, Personalized. To change Personalize Mode see "Settings".

During printing, the active mode is printed on the information line of the printout.

Options / Actions available	Description
Automatic ECG	All 12 ECG leads are recorded simultaneously (10 seconds). The signal printed out refers to the same time period, and is saved.
Manual ECG	The selected leads are recorded and printed out. The recorded signal is in real time, i.e. the trace is produced simultaneously with its acquisition.
Personalize	See “Personalize mode” for details.

Display and print format

To select the desired “display” format:

- ; the corresponding selection is displayed on screen. The options are: 3, 6. When operating in Manual Mode, the display and print formats coincide.
- to scroll the leads on the display.

To select the desired “print” format:

- to select the desired format; the corresponding choice is displayed on the screen.

The available formats are described below:

Format Type	Description
3	In “Automatic” mode: the twelve ECG leads are printed by groups of three. The total number of pages per block of leads depends on the settings. Additional pages can be added if diagnosis is produced with the help of other means (such as “Interpretation”). In “Manual” mode: three continuous leads.
6	In “Automatic” mode: the twelve ECG leads are printed by groups of six. The total number of pages per block of leads depends on the settings. Additional pages are available if diagnosis aids (e.g. Interpretation) are used. In “Manual” mode: six continuous leads.

3+R	In “Automatic” mode: the twelve ECG leads are printed by groups 2.5 sec per each lead (3x4) plus 10 sec for rhythm leads. Additional pages are available if diagnosis aids (e.g. Interpretation) are used.

The selected format will be applied to all manual, automatic and autotimed twelve lead recordings.

Speed of recording on the display and on paper

To select the scrolling speed of the displayed signal:

; the corresponding value is displayed. The options available are: 12.5 mm/s, 25 mm/s and 50 mm/s.

To select the printing speed:

; the corresponding value is displayed. The options available are: 5mm/s, 25 mm/s and 50 mm/s.

During printing, the paper transport speed is indicated on the information line.

Sensitivity of recording on the display and on paper

To select the sensitivity of recording on the display:

; the corresponding value is displayed. The options available are: , 5 mm/mV, 10 mm/mV and 20 mm/mV.

To select the sensitivity of recording on printing:

; the corresponding value is displayed. The options available are: , 5 mm/mV, 10 mm/mV and 20 mm/mV.

During printing, the recording sensitivity is indicated on the information line.

Note: *selecting the sensitivity is set automatically by the device in a way that optimises the recording over the entire width of the paper. In this case, a sensitivity of 2.5 mm/mV may be used. This option is recommended for six 3+R lead printing. To find out how automatic sensitivity is determined, see "Technical Specifications".*

Recording filter

If necessary, it is possible to use filters capable of improving the legibility of

the signal without modifying its morphology. Filter introduction affects both the displayed and the printed signal. To ensure correct and accurate tests, automatic interpretation of the trace is always performed only on the non-filtered ECG signal.

to install the filter; "on" is associated with the corresponding symbol on the display. The filters available have been designed to reduce the effect of both mains disturbances and muscle tremor.

The special isoelectric anti drift filter (ADF) remains permanently activated.

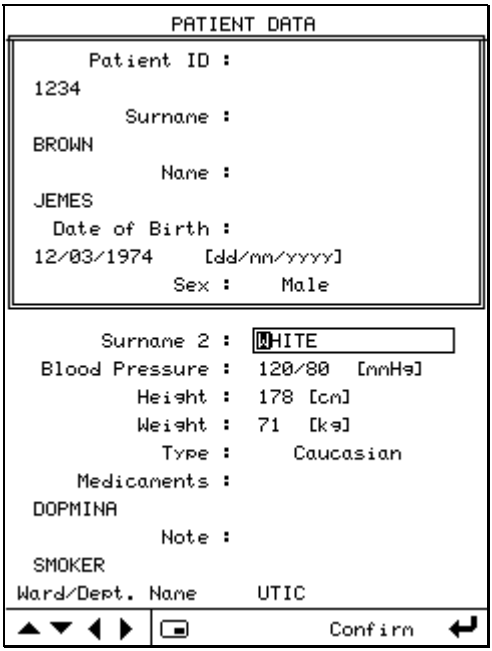
During printing, the filter installed is shown in the information line.

Warning: *the filter of your ECG is very effective in attenuating disturbances and do not reduce the diagnostic content of the traces. Nonetheless, it is advisable to eliminate the cause of the interference and not only the visible effect on the trace (see "Troubleshooting"; "Initial preparation").*

5 Recording of a rest ECG

5.1 Patient data entry

to display the patient file at any time.



Inside the patient file:

to display the "New" option. On confirmation the displayed data are cancelled.

to move around inside the file and display the options associated with the "Type".

to enter data.

- to clear the text before the cursor; to clear the text after the cursor.
- to confirm data.
- to interrupt the data entry phase with no changes.

The data entered in the patient file are, in sequence, "Patient ID", "Last Name", "First Name", "Date of birth", "Sex", "Last Name 2", "Blood Pressure", "Height", "Weight", "Type", "Medications", "Notes", "Ward/Dept Name." The patient data are retained in memory until they are modified or the equipment is turned off.

Once entered, the first name and last name are displayed on the main screen.

Warning: *new data will be saved only when the final item entered is confirmed.*

5.2 Recording in manual mode

Having selected "manual" mode (see "*Operating mode*"):

- to start the recording. If the signal has not yet been initialised, the message "Clamp" is displayed.
- to change the leads printed or displayed during recording. The leads printed are those displayed on the screen.
- interrupt the recording (stop).

Note: *during a manual recording, it is possible to change the recording characteristics: speed, sensitivity, filter.*

Warning: *starting a manual recording cancels the last trace recorded in automatic mode.*

5.3 Recording in automatic mode

An automatic recording allows the user to run available computation and analysis programs on the traces (" ECG Parameters", " ECG Interpretation"

options), to obtain a copy of the recording, to save the recording ("Memory" option), and to transfer the ECG to a Computer (PC archive" option).

Having selected "Automatic" mode (see "*Operating mode*"):

- to start the recording. If the signal has not yet been initialised, the message "Wait …" will be displayed.
- The patient data entry procedure now starts (see "*Patient data entry*").
- During the recording, progress messages are displayed: 1. "Acquisition …"; 2. "Acquisition OK". The patient can now be disconnected.
- to interrupt printing (stop). If the signal has already been saved ("Acquisition OK") it will still be possible to print a copy of the recording.

Automatic calculation of ECG parameters

The program for automatic measurement of the ECG parameters allows a report of the principal parameters calculated to be obtained at the end of each automatic recording.

- *Start:* automatic at the end of the recording.
- *Stop:* automatic at the end of printing the report. The message "Analysis OK" is displayed.

The principal items of information in the report are:

- - computed value of the following parameters: heart rate; rhythm type; P, QT, QTc, PQ, QRS and QTr wave amplitudes, frontal vectors, axes.
- - summary table of ST values for to all twelve leads ;
- - templates of all twelve leads .

Warning: *if the parameters cannot be computed, the message "Analysis nd" is displayed. This situation may be due to excessive noise affecting the ECG trace or to incorrect positioning of the electrodes.*

Automatic ECG interpretation

The automatic ECG interpreter is a function of the analysis program that can be used to obtain an evaluation of the trace at the end of each automatic recording.

- *Start:* automatic at the end of the recording.

Stop: automatic at the end of printing the report. The message "Analysis OK" is displayed.

***Warning**: The ECG Interpretation option assume that an ECG is taken on a rested person without pace-maker.*

***Warning** The correctness of the results furnished by the ECG Interpretation option also depends on the exact formulation of the physical data of the patient (sex, age), that the user is kept to effect before the execution of the analysis, according to the illustrated formalities in the User Manual.*

The automatic interpretation program in case of missing patient data, considers for the analysis a person of 35 years old gender male.

***Warning:** if the device could not perform the test due to poor signal quality on the display, the following error message is shown on the display: "Analysis na" This situation may be due to excessive noise affecting the ECG trace or to incorrect positioning of the electrodes.*

***Note:** The ECG interpreter program is structured in four parts:*

1) processing and filtering of the electrocardiographic signal

2) identification of the waveform and positioning of the markers

3) calculation of the characteristic parameters of the QRST complex

4) processing of the diagnosis and analysis of the rhythm.

The part of the program "processing of the diagnosis and analysis of the rhythm", provides the evaluation of the trace, and specifically:

a) identification of the parameters that deviate from standard (these parameters are identified in the final document by an asterisk), for example, duration of P wave, lengthening of PQ interval, widening of QRS. Furthermore, the data related to the rhythm is analysed and evaluated and the related indications are given, for example sinus arrhythmia, sinus rhythm with extra ventricular systole with compensatory pause, etc. All diagnostic indications described are defined category B, in accordance with American College of Cardiology conventions;

b) analysis of repolarisation changes, as internal or external, and the degree of intensity as reflected by variations in the ST-T segment. These diagnostic indications are defined category;

c) In the EKG program, the category A diagnostic suggestions are obtained using a multivariate alternative classification, that is a combination of statistical analysis and a ramified structure decisional technique. By virtue of its characteristics and the reliability of the results provided, the EKG program is in conformity with the requirements of IEC standards pertinent to programs for the automatic ECG trace evaluation.

Copy of an automatic ECG recording

An ECG recorded in automatic mode, and computed ECG parameters if any, can therefore be reproduced on paper any number of times.

to start printing a copy. The message "Copying …" is displayed.

to interrupt printing (stop).

If the memory does not contain valid data, the message "No data" is displayed.

Note: *the trace is saved without filtering the signal, irrespective of whether the filters are activated during the recording. The parameters can therefore be modified before printing: filters, speed and sensitivity.*

Warning:

If the "Memory Option" is not installed*: each new acquisition cancels the ECG trace saved previously!*

If the "Memory Option" is installed: *the save procedure is related to the set-up. After switching off the unit, enter the archive to obtain copy of the ECG recorded.*

ECG memory: saving a recording

At the end of the automatic recording the ECG may be saved in the memory. The archive can contain up to 40 recordings for subsequent processing or transfer to PC ("Memory option").

- *Start:* automatic, or on demand at the end of a recording (see "*Settings*").
- If "On Demand", the patient file is displayed at the end of an automatic recording. Two options are available "Save&Exit" and "Confirm&Exit". Select "Save&Exit" to save the test, or "Confirm&Exit" if you do not wish to save the test. In this case the test will remain available for copies until a new recording is made or until the device is switched off.

Warning: *the number of tests in the memory and the percentage of space used can be checked on the main screen. The message "Memory full" is displayed when the memory space is completely or close to completely filled. After finishing the current operation, free space in the memory by cancelling exams or transferring the archive to the PC.*

ECG memory: archive management

- to select the desired action: 1. Display; 2. Archive PC; 3. Print List; 4. Empty.

- to scroll pages, if more than 1.
- to enable the find function (research key: last name).
- to confirm the desired action.

For details of the options available, see "ECG Archive".

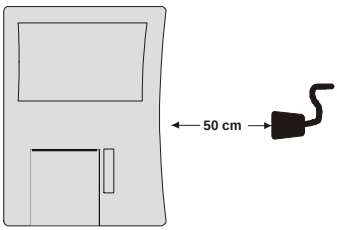
Saving to Personal Computer archive

Warning: *to ensure correct data transmission, position the IR adapter of the PC at a distance of no more than 50cm. Avoid placing objects between the two interfaces.*

Your electrocardiograph is capable of transferring stored ECG traces to a Personal Computer equipped with CARDIOLINE management software. For details on the use of the application software, consult the specific manual.

If the "Memory Option" is not installed:

- Position the electrocardiograph close to the infrared adapter (connected previously to the PC) as illustrated in the following figure:



- to start transfer .

If the "Memory Option" is installed:

The user can either proceed as described above, if the intention is to transfer the complete ECG archive.

A detailed management of the ECG transmission can be done by using the "ECG archive" menu.

- Position the electrocardiograph as indicated previously.

- Select the "ECG archive" menu and proceed as appropriate. For details of the options available, see § "*ECG archive*".

Warning: *in order to provide a correct transmission of data, position the IR adapter from PC at a distance not greater than 50 cm. Do not place any object between the two interfaces.*

5.4 Recording in Emergency mode

A Recording in "Emergency mode" is similar to an automatic recording, a part from the patient data. It allows to perform parameter calculation and analysis available (ECG measurement option, ECG interpretation option considering a person of 35 years old gender male), to print a copy, to store recording (memory option) and to transfer the exam to a PC (PC archive option).

After selecting Emergency mode: (see § "*Operation mode*"):

- to start the recording.. If the signal has not yet been initialized, the message "Wait …" will be displayed.
  - During the recording, progress messages are displayed: 1. "Acquisition …"; 2. "Acquisition OK". The patient can now be disconnected.
- to interrupt printing (stop). If the signal has already been saved ("Acquisition OK") it will still be possible to print a copy of the recording.

5.5 Recording in ECG Autotimer mode

Warning: *To obtain a correct recording in "ECG Autotimer" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

Operating in Autotimer mode, the device can make timed recordings of the 12 standard leads or of a group of three user-selectable leads.

After having selected "ECG Autotimer" mode:

- to start the recording the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.
- The programmed recordings are in real time. Together with the date/time field, details regarding the interval number and recording time (format: #xx yy min) are shown in the printouts, as well as the

wording “print from memory” if this type of print has been previously enabled during setup.

- to scroll the leads on the display during the test.
- to start manual recording inside an interval; the print format corresponds to the format selected on the display. to pause manual printing.
- to interrupt the test.

5.6 Recording in "paper saving" mode

If “Paper Saving” mode is selected the device performs and stores an automatic ECG recording including any ECG calculation and analysis programs (option "ECG Parameters", "ECG Interpretation") without any printout.

After selecting “Paper Saving” mode (see “Operating mode”):

- to start the recording. If the signal has not yet been initialised, the message “Wait …” will be displayed.
- The patient data entry procedure now starts (see “*Patient data entry*”). Patient data are mandatory.
- During the recording, progress messages are displayed: 1. “Acquisition …”; 2. “Wait…..” while the analysis is being performed (the patient can now be disconnected) 3. “Save…”.
- When saving is complete, copies of the recording can be printed, or the recordings can be transferred to the PC, using the “Copy” function or the “ECG Archive” menu.

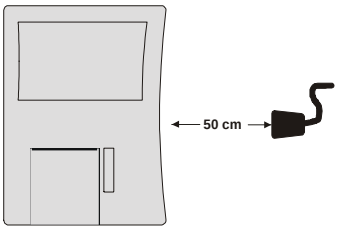
5.7 Recording in ”PC ECG” mode

Associated with the CARDIOLINE software, your **ar1200view** becomes a PC-based acquisition system. For details on the use of the application software, consult the specific manual.

Having selected “PC ECG” mode (see “*Operating mode*”):

- Position the electrocardiograph close to the infrared adapter

(connected previously to the PC) as illustrated in the following figure:



- to start transmission. The message "PC ECG transmission" is displayed. During transmission, the ECG leads are also displayed on the recorder display.

- to end transmission.

Warning: *to favour a correct transmission of data, position the IR adapter for PC to a distance not greater than 50 cm. Do not place any object between the two interfaces.*

5.8 Recording in "HRV Analysis" mode

Warning: *To obtain a correct recording in "HRV Analysis" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

A recording in HRV mode allow to analyse the measurement of the heart rate variability in a predicted interval (from 1 to 5 minutes) and to printout a complete report: full disclosure of the reference ECG lead (selected by the menu), patient data summary, table of the variability parameters (total R-R intervals, medium HR, medium R-R interval, maximum R-R interval, minimum R-R interval, ratio max/min., standard deviation, coefficient of R-R variability, number of R-R intervals greater than 2.2s and not reported on the graph) graph of the R-R distribution in the time domain, R-R trend graph.

Note: *only the electrodes referred to the lead set for the test can be connected, improving patient comfort.*

After selecting "HRV Analysis" mode:

- To start the analysis, the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.

- The display shows the time from the test start. *The test is automatically terminated at the end of the scheduled time and the final report is printed out.*

- to scroll the leads displayed during the test (based on the electrodes connected).

- to interrupt (stop). *No report is printed and the recorded data are cancelled.*

- to print copy of the report at the end of the test.

5.9 Recording in "Arrhythmia mode"

***Warning**: To obtain a correct recording in "Arrhythmia mode" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

A recording in Arrhythmia mode allow to analyze in real time the ECG signal for a predicted period of time in order to detect potential abnormalities of the Rhythm in the time domain.

During the test if an abnormal rhythm is detected a printout of the events can be obtained in continuous until the rhythm become normal again (the length of the printout depends on the setup). At the end of the test, or after every 5 minutes, a complete report is printed: full disclosure of the reference ECG lead (selected by the menu) with marker identification of the abnormal beats (*), patient data summary, table of the computed parameters.

Note: connect only the electrodes related to the reference lead in order to increase the patient comfort.

After selecting "Arrhythmia mode":

- To start the recording, the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.

- The patient data entry procedure now starts (see "Patient data entry").

- The display shows the time from the test start. The test is automatically terminated at the end of the default time (5 minutes) and the final report is printed out (in any case every 5 minutes pressing the key "stop").

to interrupt (stop).

5.10 Defibrillation!

If defibrillation occurs the ⚠ symbol is displayed. Within 10 seconds from the discharge, the signal is automatically restored.

6 Management and control of electrocardiograph functions

6.1 Disconnected electrodes, potential defibrillation

Saturation events are controlled and monitored by your electrocardiograph. The response of the electrocardiograph depends on the current phase of operation.

Stop phase

- ✓ *Symbol* ⚠ *displayed*: critical electrode contact. The user can proceed with the recording; the "critical" electrodes are indicated in the print report on the information line (for example "⚠ L 1" indicates the critical nature of the left arm electrode and of electrode C1).
- ✓ *Symbol* ***OL*** *displayed*: electrodes disconnected (saturation). It is not possible to start an automatic recording. A manual recording can be started; the "disconnected" electrodes are indicated in the display and in the print report on the information line, and a flat signal will be reproduced on paper where a lead cannot be acquired due to the absence of an electrode (e.g. "***OL L 1***" indicates saturation of the left arm electrode and of electrode C1).

Manual recording phase

The event is indicated as for the stop phase. When normal conditions have been restored, the signal is centred.

Automatic recording phase

If the event is detected during acquisition (10s), the ECG is stopped and automatically returns to the stop phase. If the signal is already buffered, the print continues without interruption. The event is indicated in the same way as for all other phases.

Defibrillation

The "***OL"*** symbol is displayed. See "Defibrillation".

6.2 Batteries low or in need of recharging

When the symbol is displayed the battery must be recharged. the reserve charge is lower than 30%.

6.3 Print system control. Out of paper

Sensors verify the correct closure of the paper compartment cover and indicate when the thermal paper is depleted. During a recording, printout is

inhibited automatically and the messages "Out of paper" or "Printer!" are displayed for 3 seconds approx.

6.4 Status messages and error indication: description and related event

Listed below are the various error messages displayed and/or printed on paper when abnormal events occur. Each message is correlated to a specific condition or phase of operation.

Messages

Message	***Description of status / event***
Not Available!	Function or action not available for the selected operating mode
Analysis nd	Automatic ECG analysis cannot be performed due to excessive signal noise
No data!	Impossible to obtain copy of the last recording
⚠	- Critical electrodes - Attention
0L	Disconnected electrodes or potential defibrillation
Out of paper!	Paper finished, insert a new pack / roll
Printer!	Paper compartment cover open or not properly closed
	Low battery
	Run-down battery

6.5 Troubleshooting

The following table summarises certain problems that may occur and the relative causes.

Problem	***Cause***
Isoelectric line drift	- Use of electrodes other than originals Use of electrodes in saturation - Insufficient electrode/skin contact - Electrode surface dirty - Patient moving
Interference from AC mains supply	- Voltage generator too close; presence of other clinical instruments (e.g. X-rays, etc.) - Patient in contact with metallic parts or with other persons
Muscle tremors	- Patient not relaxed - Peripheral electrodes adhering too tightly
Irregular paper transport	- End of paper roll - Paper roll incorrectly positioned - Use of non-original paper
Analysis impossible	Signal too unstable or noisy
No copy of trace	- Wrong copy setup - Recording is interrupted before 10 seconds - "Real time" operation mode: Manual Autotimer Arrhythmia HRV - If the memory option is enabled, if the device is off after the last acquisition.
Abnormal signal	- Defective patient cable - Defective electrodes

7 Maintenance

7.1 Self-test

Run the User self-test procedure periodically. This performs a routine check on the functional efficiency of the display, the keys, the writing system and the memory. The user can also print out identifying information relative to the individual device.

In the event of error messages being displayed, contact the **CARDIOLINE®** Authorised Assistance Centre, and a technician will investigate and eliminate the causes of the trouble.

The self-test menu is accessed by selecting "Tools" -> "Self-test" -> "User". Before running the self-test procedure, ensure that there is paper loaded.

- to select the type of test required.
- to start the test.
- Tests available:
  - Display: pixel scan. The presence of blank areas signifies faulty operation of the display.
  - Keyboard: the position of the single keys is simulated in the display. Pressing a given key, the corresponding area of the display is energised. A lack of response in any one area indicates that the relative key is faulty.
  - Printer: the writing system generates two triangular waves, the character set in the memory, and signals with different speeds and sensitivities. Irregularities of the printing system are detectable in non-continuous lines.
  - Memory: a message relating to the status of the memory is printed.
  - About. The following items of information are printed: model identification, serial number of the device, details of software, version and language code.

Warning: *do not run the service self-test without a qualified technician in attendance.*

7.2 Replacing the thermal paper

When the thermal paper is depleted, the device stops and any attempt to start recording is inhibited (see "*Print system control.* "*Out of paper*".)

7.3 How to clean the device and the electrodes

To clean the device, use a cloth moistened with water or denatured ethyl alcohol. Do not use other chemical products or household detergents.

For the electrodes: remove the electrodes from the patient cable and wash under running water. Do not scratch the electrodes and do not wash the leads box and the patient socket.

Note: *the device cannot be sterilised! The electrodes can be sterilised with ethylene oxide.*

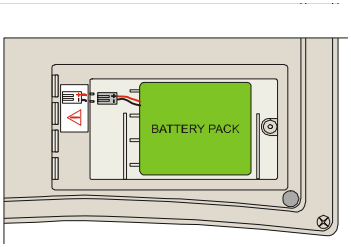
7.4 Battery replacement

The battery pack should be replaced when the recorder is not used with the mains supply and the battery is low or run-down, therefore insufficient for operation.

The average life of a battery pack is about one year.

Warning: *Use only original batteries supplied with a protection device!*

Warning: *Before removing from or introducing the batteries in the recorder, make sure that the device is off and the power supply cable is disconnected from the mains. Not doing so may cause electric shock to the patient or operator.*



1. Open the battery compartment.
2. Annotate the battery pack connection polarities (red +, black -), then remove the batteries from their housing by pulling the connector.
3. Introduce the new batteries and reconnect the connector with the correct polarities (red +, black -).
4. Close the battery compartment.

5. Before using the recorder again, read carefully the recharge instructions given in *§ "Battery recharge".*
6. Reset date and time in the appropriate menu.

Warning: *If the battery pack connection polarities are not matched correctly, severe damage can be caused to the recorder and the guarantee will be invalidated.*

Warning: *Do not abandon the exhausted batteries in the environment. Use only original batteries supplied by the manufacturer.*

Note: *Removing the battery pack will not determine a loss of data.*

7.5 Display maintenance

- ✓ Keep the display dry and avoiding the formation of condensation. If condensation forms, the liquid crystals could be damaged.
- ✓ Use a soft cloth to clean the surface of the display. Use of rough cloths could scratch the surface.
- ✓ Do not use solvent-based chemical products.

Warning: *in case the display panel breaks, do not swallow the liquid released. If this liquid comes into contact with skin or clothing, wash immediately using abundant quantities of soapy water.*

High pressure during use can cause fonts to be displayed abnormally. Normal operations will be re-established.

7.6 Periodic checks

To ensure correct and long-lasting operation of the device, it is necessary to have an Authorised Assistance Centre carry out the following checks:

- ✓ paper drive speed calibration: every year;
- ✓ cleaning of paper compartment, paper presence sensor and writing system: every year;
- ✓ integrity of cables and connectors: every year, by means of an ECG simulator;
- ✓ general check of functional efficiency of the device and leakage currents: every 2 years.

Technical information

et medical devices SpA undertakes, when requested by qualified persons, to furnish the list of components used in the device, and the information necessary to repair the parts of the device considered serviceable.

8 Technical specifications

Mains power supply	Internal supply, class I 230 V ± 10% 50/60Hz 115 V ± 10% 50/60 Hz
Maximum current absorbed	160 mA at 115 V ~ ±10% 80 mA at 230 V ~ ±10%
Mains protection	Fuse: T 0.5 A
Internal power supply	12V – 1800 mAh NiMh rechargeable battery pack
Internal power supply protection	Pico fuse SHF SLO-BLO T 5 A Littelfuse
Applied part	CF type
Defibrillation protection	In the device
Input dynamic	± 300 mV @ 0 Hz.± 5 mV in pass band
Input impedance	> 100 MΩ on each electrode
Common mode rejection	> 100 dB with balanced electrode impedance
Frequency response	0.05 - 150 Hz (-3db)
Time constant	3.3 s
Acquisition	11 bit 1000 samples/s/channel printing and filters 500 samples/s/channel in calculation and filters Resolution 5 μV/bit
Leads	12 leads in Standard, Cabrera or Personalize sequence
Signal memory	10 seconds for each lead in auto
Recording/display sensitivity	Manual: 5 – 10 – 20 mm/mV ± 5% Automatic: 2.5 - 5 – 10 – 20 mm/mV ± 5%, *dependent on number of channels printed*
Writing system	Thermal printer, 8 dot/mm Usable print height 108 mm
Print channels	6
Print format	3, 6, 3+R
Display channel	3, 6
Paper transport speed	5 mm/s ± 10% 25 – 50 mm/s
Screen scrolling speed	12.5 – 25 – 50 mm/s
Thermal paper	*In rolls*: 20 m long, page 120x100 mm, gridded. *Z-fold pack:* 30 m long, gridded 120x100 mm page.
Pacemaker recognition	Recognises pulse in accordance with current IEC standards
Filters	*Mains interference:* Modified linear phase digital notch filter 50 - 60 Hz may be switched on/off. *Anti-drift:* Digital high-pass 0.5 Hz, linear phase, always enabled.
Serial interface	Infrared
Keyboard	Membrane, with functional and alphanumeric keyboard extended
Display	Single-colour, graphic, 320x240 pixels (4.7 inches) LCD. Actual display area: 100x75 mm.

	Backlit with cold cathode fluorescent light
Interpretation program	Parameter calculation (optional) *ECG interpretation* (optional): Arrhythmia Program (optional) HRV: RR variability (optional)
Type of use	Continuous
Operating modes	*Manual:* acquisition and printing in real time *Automatic* : simultaneous acquisition *Timed:* acquisition at user-defined intervals *Arrhythmia:* analyse in real time arrhythmic phenomenon's with recording in continuous *PC-ECG:* real time acquisition with display at PC *HRV*: heart rate variability analysis *Emergency:* acquisition in emergency
Options	- Memories option - ECG measurements option - ECG interpretation option - Arrhythmia option - HRV option - PC archive option - PC ECG option
Battery capacity	*Internal battery:* 100 min. with 3-channel print.
Recharging time	*Internal battery:* 18 hours 100%
Housing protection degree	IP 20
Ambient conditions:	
- operation	*Ambient temperature:* from +10°C to +40°C *Relative humidity:* from 25% to 95% (without condensation) *Atmospheric pressure:* from 700hPa to 1060 hPa
- transport and storage	*Ambient temperature:* from -10°C to +40°C *Relative humidity:* from 10% to 95% (without condensation) *Atmospheric pressure:* from 500 to 1060 hPa
Dimensions	320 x 72 x 240 mm (length x height x depth)
Weight	2150 grams, without paper
Conformity to standards	EN 60601-1: 1990 EN 60601-1/A1: 1992 EN 60601-1/A2: 1995 EN 60601-1/A13: 1995 *General standards for safety of electromedical equipment* EN 60601-1-2: 1993 *Standards on electromagnetic compatibility of electromedical equipment* EN 60601-2-25: 1995 EN 60601-2-25/A1: 1999 *Particular safety standards for electrocardiographs* IEC/60601-2-51/Ed.1: 2001 *Particular standards on essential recording and analysis performance safety of single and multichannel electrocardiographs.*

Basic accessories supplied*

- IEC Patient cable, ref. 63050025
- 6 suction cup electrodes ref. 66030163
- 4 peripheral electrodes ref. 660301105
- 1 260 gr. gel bottle, ref. 66020002
- 1 paper roll, 120 mm x 20m, ref. 66010033
- 1 Z-fold paper pack, 120 x 100 mm x 30 metres ref. 66010039
- ECG ruler
- User's Manual

Note: *may vary according to sale configuration selected upon purchase*

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